

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Original) A process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide (levetiracetam) comprising reacting (S)-2-amino-butanamide hydrochloride and 4-chlorobutryl chloride in a solvent selected from the group consisting of acetonitrile and methyl tertbutyl ether, in the presence of a strong base, and recovering the crude levetiracetam.
2. (Original) A process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide which comprises cyclizing (S)-N-[1-(aminocarbonyl)propyl]- 4-chlorobutanamide, in a solvent selected from the group consisting of acetonitrile and methyl tertbutyl ether, in the presence of a strong base, and recovering the crude levetiracetam.
3. (Original) A process of claim 2, wherein the reaction is performed in the absence of a catalyst.
4. (Original) A process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide (levetiracetam) comprising reacting (S)-2-amino-butanamide hydrochloride and 4-chlorobutryl chloride, in an inert solvent, in the absence of a catalyst, and recovering the crude levetiracetam.

5. (Original) The process of claim 4, wherein the reaction takes place in the presence of a strong base.
6. (Original) The process of claim 4, wherein the inert solvent is selected from the group consisting of acetonitrile and methyl tertbutyl ether.
7. (Original) The process of claim 1, wherein the crude levetiracetam comprises less than about 0.4% by weight of (R)- α -ethyl-2-oxo-1-pyrrolidineacetamide.
8. (Original) The process according to claim 1, wherein the crude levetiracetam comprises less than about 0.2 % by weight of impurities.
9. (Original) The process of claim 1, further comprising purifying the crude levetiracetam by crystallizing or recrystallizing it from an organic solvent or a mixture of organic solvents to obtain purified levetiracetam.
10. (Original) The process of claim 9, wherein the organic solvent is selected from the group consisting of ethanol, ethyl acetate, toluene, methylethyl ketone, tetrahydrofuran, isopropylalcohol, dichloromethane, methanol, nitromethane, hexane, and methyl tertbutyl ether.

11. (Currently Amended) The process of claims 1 ~~or 5~~, wherein the strong base is present in an amount of at least about 3 molar equivalents based on the amount of (S)-2-amino-butanamide hydrochloride.
12. (Original) The process of claim 1, wherein the reaction temperature is maintained at between about -15 degrees celcius and about + 15 degrees celcius.
13. (Original) The process of claim 1, wherein the reaction takes place in the presence of a drying agent.
14. (Original) The process of claim 13, wherein the drying agent is selected from the group consisting of magnesium sulphate, molecular sieves, potassium carbonate, sodium carbonate, and sodium sulphate.
15. (Original) The process of claim 14, wherein the reaction temperature is maintained at between about 0 degrees celcius and about + 5 degrees celcius.
16. (Original) The process of claim 14, further comprising purifying the crude levetiracetam by recrystallizing it from an organic solvent or a mixture of organic solvents to obtain purified levetiracetam.

17. (Original) The process of claim 17, wherein the organic solvent is selected from the group consisting of ethanol, ethyl acetate, toluene, methylethyl ketone, tetrahydrofuran, isopropylalcohol, dichloromethane, methanol, nitromethane, hexane, and methyl tertbutyl ether.
18. (Original) The process of claim 18, wherein the organic solvent is ethyl acetate.
19. (Original) The process of claim 19, wherein the drying agent is potassium carbonate.
20. (Original) The process of claim 13, wherein the drying agent is molecular sieves.
21. (Original) The process of claim 14, wherein the drying agent is sodium sulphate.
22. (Original) The process of claim 1, further comprising adding an acid or a mixture of acids to the completed reaction mixture to adjust the pH to less than about 8.
23. (Original) The process of claim 22, wherein the pH is adjusted to less than about 7.
24. (Original) The process of claim 22, wherein the acid or mixture of acids is selected from the group consisting of a mixture of hydrochloric acid and acetic acid, and formic acid.

25. (Currently Amended) Levetiracetam made by the process of any of claim 1-24.

26. (Original) A pharmaceutical composition comprising the product of claim 25 and a pharmaceutically acceptable carrier.

27. (Original) A pharmaceutical formulation comprising levetiracetam and a pharmaceutically acceptable carrier, wherein the formulation comprises less than 0.2% by weight of impurities.

28. (Original) The pharmaceutical formulation of claim 27, wherein the formulation comprises less than 0.1% by weight of impurities.